K090452

# Section 6: 510(k) Summary

MAY 22 2009

**Applicant:**

Neoss Ltd
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**US Contact:**

Cherita James
M Squared Associates, Inc.
901 King Street, Suite 200
Alexandria, Virginia 22314
Phone: 703-562-9800 Ext. 257
Facsimile: 703-562-9797

**Manufacturing:**

Implants, abutments and abutment screws

Elos AB
Bäckedalsvägen 6
SE-540 16Timmersdala, Sweden.
**Registration Number:** 3003847101

Pinol AS
Engsvej 33
DK-3330 Gorlose, Denmark.
**Registration Number:** Not yet available

Samaplast AG
Neugruetstr 3
St Margrethen SG
CH 9430
**Registration Number :** Not yet available

Packaging Facility

Wesley Coe Ltd
Gas Lane
Ely, Cambridgeshire
CB7 4GH, UK
**Registration Number:** 8044131

Sterilization Facility

Swann-Morton Ltd

K090452

Owlerton Green
Hillsborough,
Sheffield, S6 2BJ, UK
**Registration Number:** 9611194

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|---|---|
| **Date submitted:** | 19 February 2009 |
| **Proprietary Name:** | Neoss Implant System Ø3,25 |
| **Common Name:** | Dental implant |
| **Classification Status:** | Class II |
| **Product Codes:** | DZE, NHA |
| **Regulation:** | 872.3640 Implant, Endosseous, Root Form; 872.3630 Abutment, implant , dental, endosseous |
| **Predicate Device:** | Neoss Bimodal Implant K043195, Neoss ProActive Implant K083561 and Neoss Abutment System K071838. |

**Device Description:**

The Neoss Implant System Ø3,25 assortment consists of a number of implants with a diameter of Ø3,25 mm and lengths between 9,0 – 17.0 mm having the same internal abutment designs as previously cleared per K083561 & K043195 & K071838, but a smaller diameter and includes a selection of abutments.

Identical to K043195 & K083561, the Neoss Implant System Ø3,25 remains a threaded, internal abutment connection, root-form titanium dental implant. The internal connection being equipped with interlocking elements for an insertion tool and the non-rotational locking of the abutment. Smaller associated bone cutting instruments are also available. The Neoss Implant System Ø3,25 available surface treatment will be identical to either the Neoss Bimodal or Neoss ProActive Implant. Supplied sterile.

**Indication for Use:** The Neoss Implant System Ø3,25 is for single-stage and two-stage surgical procedures and cement or screw retained restorations. The Neoss Implant System Ø3,25 is intended for immediate loading on single tooth and /or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

The Neoss Implant Ø3,25 abutments are designed to be connected to the Neoss implants and

intended for use as an aid in prosthetic rehabilitation.

**Summary of Technological Characteristics:**

The modification to the Neoss Bimodal Implant, since its previous clearance in K043195 and Neoss ProActive Implant , previously cleared under K083561 and Neoss Abutment cleared under K071838 are as follows:

a) Diameter of Implant Thread Ø3,5 to Ø3,25
b) Diameter of Abutment connection Ø4,0 to Ø3,5
c) Outer Diameter of Abutment screw M2 to M1,6
d) Smaller Countersink and Screw Tap instruments for compatibility with modified implant dimensions

These dimensional changes do not affect the safety nor performance of the device or instruments and do not change the intended use of the Neoss Implant System Ø3,25 when compared to Neoss Bimodal Implant, Neoss ProActive Implant and Neoss Abutments when used as intended. They allow the clinician a range of options comparable to other currently marketed devices in relation to narrow bone ridges & narrower mesio distal spaces.

**Summary of Nonclinical Testing:**

Based on the Risk Analysis, performance testing and fatigue testing was conducted to confirm compliance to device specifications and recognized standards; all functions were verified to operate as designed.

**Substantial Equivalence Discussion:**

The introduction of the Neoss Implant System Ø3,25 does not change the intended use nor does it affect the safety and effectiveness as compared to the Neoss Bimodal Implant previously cleared in K043195 and Neoss ProActive Implant, previously cleared in K083561 and Neoss Abutments , previously cleared in K071838. Performance of the modified device is as safe and effective as other currently marketed devices of comparable dimension.

**Conclusion:**

The introduction of Neoss Implant System Ø3,25 has the following similarities to the Neoss Bimodal Implant previously cleared in K043195 and Neoss ProActive Implant previously cleared in K083561 and Neoss Abutments , previously cleared in K 071838:

- has the same indicated use,
- uses the same operating principle,
- incorporates the same basic device design and physical properties,
- incorporates the same materials.

Therefore, the Neoss Implant System Ø3,25 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

Neoss Limited
C/o Ms. Cherita James
Regulatory Consultant
M Squared Associates, Incorporated
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K090452
Trade/Device Name: Neoss Implant System Ø3,25
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 19, 2009
Received: May 20, 2009

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Section 5: Indications for Use Statement

510(k) Number (if known): K090452

Device Name: Neoss Implant System Ø3,25

Indications For Use:

The Neoss Implant System Ø3,25 is for single-stage and two-stage surgical procedures and cement or screw retained restorations.

The Neoss Implant System Ø3,25 are intended for immediate loading on single tooth and /or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

The Neoss Implant Ø3,25 abutments are designed to be connected to the Neoss implants and intended for use as an aid in prosthetic rehabilitation.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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